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DESCRIPTION

SPINAL DISC ANNULUS RECONSTRUCTION METHOD AND SPINAL DISC ANNULUS STENT

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Cross-Reference to a Related Application

[001] This application is a continuation-in-part of US Patent Application No. 09/947,078, filed September 5, 2001, which is a continuation of U.S. Patent Application No. 09/484,706, filed January 18, 2000, which claims the benefit of U.S. Provisional Application No. 60/160,710, filed October 20, 1999, the entire contents of each are incorporated herein by reference.

Field of the Invention

[002] The invention generally relates to a surgical method of intervertebral disc wall reconstruction. The invention also relates to an annular repair device, or stent, for annular disc repair. The effects of said reconstruction are restoration of disc wall integrity and reduction of the failure rate (3-21%)(3-21%) of a common surgical procedure (disc fragment removal or discectomy). This surgical procedure is performed about 390,000 times annually in the United States.-

20 BACKGROUND OF THE INVENTION

Background of the Invention

[003] The spinal column is formed from a number of vertebrae, which in their normal state are separated from each other by cartilaginous intervertebral discs. The

intervertebral disc acts in the spine as a crucial stabilizer, and as a mechanism for force distribution between the vertebral bodies. Without the disc, collapse of the intervertebral space occurs in conjunction with abnormal joint mechanics and premature development of arthritic changes.-

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[004] The normal intervertebral disc has an outer ligamentous ring called the annulus surrounding the nucleus pulposus. The annulus binds the adjacent vertebrae together and is constituted of collagen fibers that are attached to the vertebrae and cross each other so that half of the individual fibers will tighten as the vertebrae are rotated in 10 either direction, thus resisting twisting or torsional motion. The nucleus pulposus is constituted of loose tissue, having about 85% water content, which moves about during bending from front~~front~~ to back and from side to side~~side~~.

[005] The aging process contributes to gradual changes in the intervertebral discs. 15 The annulus loses much of its flexibility and resilience, becoming more dense and solid in composition. The aging annulus is also marked by the appearance on propagation of cracks or fissures in the annular wall. Similarly, the nucleus dessicates, increasing viscosity and thus losing its fluidity. In combination, these features of the aged intervertebral discs result in less dynamic stress distribution because of the more viscous 20 nucleus pulposus, and less ability to withstand localized stresses by the annulus fibrosus due to its dessication, loss of flexibility and the presence of fissures. Occasionally fissures may form rents through the annular wall. In these instances, the nucleus pulposus is urged

outwardly from the subannular space through a rent, often into the spinal column.

Extruded nucleus pulposus can, and often does, mechanically press on the spinal cord or spinal nerve rootlet. This painful condition is clinically referred to as a ruptured or herniated disc.-

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[006] In the event of annulus rupture, the subannular nucleus pulposus migrates along the path of least resistance forcing the fissure to open further, allowing migration of the nucleus pulposus through the wall of the disc, with resultant nerve compression and leakage of chemicals of inflammation into the space around the adjacent nerve roots 10 supplying the extremities, bladder, bowel and genitalia. The usual effect of nerve compression and inflammation is intolerable back or neck pain, radiating into the extremities, with accompanying numbness, weakness, and in late stages, paralysis and muscle atrophy, and/or bladder and bowel incontinence. Additionally, injury, disease or other degenerative disorders may cause one or more of the intervertebral discs to shrink, 15 collapse, deteriorate or become displaced, herniated, or otherwise damaged and compromised.-

[007] The surgical standard of care for treatment of herniated, displaced or ruptured intervertebral discs is fragment removal and nerve decompression without a 20 requirement to reconstruct the annular wall. While results are currently acceptable, they are not optimal. Various authors report 3.1-21% 3.1- 21% recurrent disc herniation, representing a failure of the primary procedure and requiring re-operation for the same

condition. An estimated 10% recurrence rate results in 39,000 re-operations in the United States each year.-

5 [008] An additional method of relieving the symptoms is thermal annuloplasty, involving the heating of ~~sub-annular zones in the non-herniated~~sub-annular zones in ~~the non-hermated~~ painful disc, seeking pain relief, but making no claim of reconstruction of the ruptured, discontinuous annulus wall.-

10 [009] There is currently no known method of annulus reconstruction, either primarily or augmented with an annulus stent.-

BRIEF SUMMARY OF THE INVENTION

Brief Summary of the Invention

15 [010] The present invention provides methods and related materials for reconstruction of the disc wall in cases of displaced, herniated, ruptured, or otherwise damaged intervertebral discs. In accordance with the invention, an annulus stent is disclosed for repair of an intervertebral disc annulus, comprising a centralized hub section, said hub section comprising lateral extensions from the hub section.

20 In an exemplary embodiment, one or more mild biodegradable surgical sutures are placed at about equal distances along the sides of a pathologic aperture in the ruptured disc wall (annulus) or along the sides of a surgical incision in the annular wall, which may be weakened or thinned.

[011] thinned.

Sutures are then tied in such fashion as to draw together the sides of the aperture, effecting reapproximation or closure of the opening, to enhance natural healing and subsequent reconstruction by natural tissue (fibroblasts) crossing the now surgically narrowed gap in the disc annulus.

5 [012] annulus.

[013] A 25-30% reduction in the rate of recurrence of disc nucleus herniation through this aperture, has been achieved using this method.-

10 [014] In another embodiment ~~as depicted in FIG. 7B~~, the method can be augmented by creating a subannular barrier in and across the aperture by placement of a patch of human muscle fascia (the membrane covering the muscle) or any other autograft or allograft ~~autograft, allograft, or xenograft~~ ~~acting as a bridge in and across the aperture, or~~ a scaffold, providing a platform for traverse of fibroblasts or other normal cells of repairing existing in and around the various layers of the disc annulus, prior to closure of the

15 aperture.-

[015] A 30-50% reduction ~~in~~ the rate of recurrence of disc herniation has been achieved using the aforementioned fascial augmentation with this embodiment.-

20 [016] Having demonstrated that human muscle fascia is adaptable for annular reconstruction, other biocompatible membranes can be employed as a bridge, stent, patch or barrier to subsequent migration of the disc nucleus through the aperture. Such biocompatible materials may be, for example, medical grade biocompatible fabrics, biodegradable polymeric sheets, or form fitting or non-form fitting fillers for the cavity

created by removal of a portion of the disc nucleus pulposus in the course of the disc fragment removal or discectomy. The prosthetic material can be placed in and around the intervertebral space, created by removal of the degenerated disc fragments.-

5 [017] Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.-

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[018] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.-

15 BRIEF DESCRIPTION OF THE DRAWINGS

Brief Description of the Drawings

[019] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate illustrative embodiments of the invention and, together with the description, serve to explain the principles of the invention.-

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[020] FIG. 1 shows a perspective view of an illustrative embodiment of an annulus stent.-

[021] FIG. 2 shows a front view of the annulus stent of FIG. 1.

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[022] FIG. 3 shows a side view of the annulus stent of FIG. 1.

[023] FIGS.FIGs. 4A-4C show a front view of alternative illustrative embodiments of an annulus stent.-

10 [024] FIGS.FIGs. 5A-5B show the alternative embodiment of a further illustrative

embodiment of an annulus stent.-

[025] FIGS.FIGs. 6A-6B show the alternative embodiment of a further illustrative embodiment of an annulus stent.-

15 [026] FIGS. 7A-7B show, respectively, FIG. 7 shows a primary closure of an opening in the disc annulus using a suture, and a subannular tissue stent or patch.
annulus.

[027] FIGS.FIGs. 8A-8B show a primary closure with a stent.-

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[028] FIG. 9 shows a method of suturing an annulus stent into the disc annulus, utilizing sub-annular fixation points.-

[029] FIGS. FIGs. 10A-10B show a further illustrative embodiment of an annulus stent with flexible bladder being expanded into the disc annulus.-

5 [030] FIGS. FIGs. 11A-11D show an annulus stent being inserted into the disc annulus.-

[031] FIGS. 12A-12B FIGs. 12A- 12B show an annulus stent with a flexible bladder being expanded.-

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~~DETAILED DESCRIPTION OF THE INVENTION~~

[032] FIG. 13 shows a perspective view of a further illustrative embodiment of an annulus stent.

[033] FIG. 14 shows a first collapsed view of the annulus stent of FIG. 13.

15

[034] FIG. 15 shows a second collapsed view of the annulus stent of FIG. 13.

[035] FIGs. 16A-16C show the annulus stent of FIG. 13 being inserted into the disc annulus.

[036] FIGs. 17A-17C show a method of inserting the annulus stent of FIG. 13 into the disc annulus.

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[037] FIGs. 18A-18B show a further illustrative embodiment of an annulus stent with a flexible bladder.

[038] FIGs. 19A-19B show another illustrative embodiment of an annulus stent with a flexible bladder.

[039] FIG. 20 shows an expanded annulus stent with on radial extensions.

[040] FIG. 21 shows a still further illustrative embodiment of an annulus stent with a compressible core.

Detailed Description of the Invention

[041] Reference will now be made in detail to an illustrative embodiment of the invention, which appears in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.-

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[042] In one embodiment of the present invention, as shown in FIG. 7A, a damaged annulus 42 is repaired by use of surgical sutures 40. One or more surgical sutures 40 are placed at about equal distances along the sides of a pathologic aperture 44 in the annulus 42. Reapproximation or closure of the aperture 44 is accomplished by tying the sutures 40 so that the sides of the aperture 44 are drawn together. The reapproximation or closure of the aperture 44 enhances the natural healing and subsequent reconstruction by the natural tissue (e.g., fibroblasts) crossing the now surgically narrowed gap in the annulus 42. Preferably, the surgical sutures 40 are biodegradable, but permanent ~~non~~-biodegradable may be utilized. non- biodegradable may be utilized.

[043] Additionally, to repair a weakened or thinned wall of a disc annulus 42, a surgical incision is made along the weakened or thinned region of the annulus 42 and one or more surgical sutures 40 can be placed at about equal distances laterally from the incision. Reapproximation or closure of the incision is accomplished by tying the sutures 5 40 so that the sides of the incision are drawn together. The reapproximation or closure of the incision enhances the natural ~~healing~~heal- Ing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus 42. Preferably, the surgical sutures 40 are biodegradable, but permanent non-biodegradable materials may be utilized.-

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[044] In an alternative embodiment ~~as depicted in FIG. 7B~~, the method can be augmented by the placement of a patch of human muscle fascia or any other autograft, allograft or xenograft in and across the aperture 44. The patch acts as a bridge in and across the aperture 44, providing a platform for traverse of fibroblasts or other normal cells 15 of repair existing in and around the various layers of the disc annulus 42, prior to closure of the aperture 44.-

[045] In a further embodiment, as shown in FIGS.FIGs. 8A-B a biocompatible membrane can be employed as an annulus stent 10, being placed in and across the 20 aperture 44. The annulus stent 10 acts as a bridge in and across the aperture 44, providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the disc annulus 42, prior to closure of the aperture 44.-

In an illustrative embodiment, as shown in FIGS. FIGS. 1-3, the annulus stent 10 comprises a centralized vertical extension 12, with an upper section 14 and a lower section 16. The centralized vertical extension 12 can be trapezoid in shape through the width and may be 5 from about 8 mm-12 mm in 8mm - length.

[046] 12mm in length.

[047] Additionally, the upper section 14 of the centralized vertical extension 12 may be any number of different shapes, as shown in FIGS. FIGS. 4A and 4B, with the sides of the upper section 14 being curved or with the upper section 14 being circular in shape. 10 Furthermore, the annulus stent 10 may contain a recess between the upper section 14 and the lower section 16, enabling the annulus stent 10 to form a compatible fit with the edges of the aperture 44.-

[048] The upper section 14 of the centralized vertical extension 12 can comprise a 15 slot 18, where the slot 18 forms an orifice through the upper section 14. The slot 18 is positioned within the upper section 14 such that it traverses the upper section's 14 longitudinal axis. The slot 18 is of such a size and shape that sutures, tension bands, staples or any other type of fixation device known in the art may be passed through, to affix the annulus stent 10 to the disc annulus 42.-

20

[049] In an alternative embodiment, the upper section 14 of the centralized vertical extension 12 may be perforated. The perforated upper section 14 contains a plurality of holes that traverse the longitudinal axis of upper section 14. The perforations are of such a

size and shape that sutures, tension bands, staples or any other type of fixation device known the art may be passed through, to affix the annulus stent 10 to the disc annulus 42.-

[050] The lower section 16 of the centralized vertical extension 12 can comprise a 5 pair of lateral extensions, a left lateral extension 20 and a right lateral extension 22. The lateral extensions 20 and 22 comprise an inside edge 24, an outside edge 26, an upper surface 28, and a lower surface 30. The lateral extensions 20 and 22 can have an essentially constant thickness throughout. The inside edge 24 is attached to and is about the same length as the lower section 16. The outside edge 26 can be about ~~8 mm-16~~ 10 ~~mm~~8mm-16mm in length. The inside edge 24 and the lower section ~~16B~~ meet to form a horizontal plane, essentially perpendicular to the centralized vertical extension 12. The upper surface 28 of the lateral extensions 20 and 22 can form an angle from about 0-degree-60-degree.0°-60° below the horizontal plane. The width of the annulus stent 10 may be from about ~~3 mm-5 mm~~3mm-5mm.

15

[051] Additionally, the upper surface 28 of the lateral extensions 20 and 22 may be barbed for fixation to the inside surface of the disc annulus 42 and to resist expulsion through the aperture 44.-

20

[052] In an alternative embodiment, as shown in FIG. 4B, the lateral extensions 20 and 22 have a greater thickness at the inside edge 24 than at the outside edge 26.-

[053] In an illustrative embodiment, the annulus stent 10 is a solid unit, formed from one or more of the flexible resilient biocompatible or bioresorbable materials well known in the art.-

5 [054] For example, the annulus stent 10 may be made from: from:

[055] a porous matrix or mesh of biocompatible and bioresorbable fibers acting as a scaffold to regenerate disc tissue and replace annulus fibrosus as disclosed in, for example, U.S. Pat. No. U. S. Patent Nos. 5,108,438 (Stone) and U.S. Pat. No. 5,258,043 (Stone), a strong network of ~~inert~~Miert fibers intermingled with a ~~bioresorbable~~ (or ~~bioabsorbable~~)bioresorbable (or ~~blosabsorable~~) material which attracts tissue ingrowth as disclosed in, for example, U.S. Pat. No. ~~Patent No.~~ 4,904,260 (Ray et al.); ~~al.~~;

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[056] a biodegradable substrate as disclosed in, for example, U.S. Pat. ~~Patent No.~~ No. 5,964,807 (Gan et al.); or ~~or~~

[057] an expandable polytetrafluoroethylene (ePTFE), as used for conventional 15 vascular grafts, such as those sold by W.-L. Gore and Associates, Inc. under the trademarks GORE-TEX and PRECLUDE, or by Impra, Inc. under the trademark IMPRA.-

[058] Furthermore, the annulus stent 10, may contain hygroscopic material for a controlled limited expansion of the annulus stent 10 to fill the evacuated disc space cavity.-

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[059] Additionally, the annulus stent 10 may comprise materials to facilitate regeneration of disc tissue, such as bioactive silica-based materials that assist in

regeneration of disc tissue as disclosed in U.S. Pat. Patent No. 5,849,331 (Ducheyne, et al.), or other tissue growth factors well known in the art.-

5 [060] In further embodiments, as shown in FIGS. FIGS. 5AB-6AB, the left and right lateral extensions 20 and 22 join to form a solid pyramid or cone. Additionally, the left and right lateral extensions 20 and 22 may form a solid trapezoid, wedge, or bullet shape. The solid formation may be a solid biocompatible or bioresorbable flexible material, allowing the lateral extensions 20 and 22 to be compressed ~~for insertion~~for uil insertion into aperture 44, then to expand conforming to the shape of the annulus' 42 inner wall.-

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15 [061] Alternatively, a compressible core may be attached to the lower surface 30 of the lateral extensions 20 and 22, forming a pyramid, cone, trapezoid, wedge, or bullet shape. The compressible core may be made from one of the biocompatible or ~~bioresorbable~~bloresorbable resilient foamsfoarris well known in the art. The core can also comprise a fluid-expandable membrane, e.g., a balloon. The compressible core allows the lateral extensions 20 and 22 to be compressed for insertion into aperture 44, then to expand conforming to the shape of the annulus' 42 inner wall and to the cavity created by pathologic extrusion or surgical removal of the disc fragment.-

20

[062] In an illustrative method of use, as shown in FIGS. 11 A-D, FIGS. 11A-D, the lateral extensions 20 and 22 are compressed together for insertion into the aperture 44 of the disc annulus 42. The annulus stent 10 is then inserted into the aperture 44, where the

lateral extensions **20**, **22** expand. In an expanded configuration, the upper surface **28** can substantially conform to the contour of the inside surface of the disc annulus **42**. The upper section **14** is positioned within the aperture **44** so that the annulus stent **10** may be secured to the disc annulus **42**, using means well known in the art.-

5

[063] In an alternative method, where the length of the aperture **44** is less than the length of the outside edge **26** of the annulus stent **10**, the annulus stent **10** can be inserted laterally into the aperture **44**. The lateral extensions **20** and **22** are compressed, and the annulus stent **10** can then be laterally inserted into the aperture **44**. The annulus stent **10** can then be rotated inside the disc annulus **42**, such that the upper section **14** can be held back through the aperture **44**. The lateral extensions **20** and **22** are then allowed to expand, with the upper surface **28** contouring to the inside surface of the disc annulus **42**. The upper section **14** can be positioned within, or proximate to, the aperture **44** in the subannular space such that the annulus stent **10** may be secured to the disc annulus, using means well known in the art.-

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[064] In an alternative method of securing the annulus stent **10** in the aperture **44**, as shown in FIG. 9, a first surgical screw **50** and second surgical screw **52**, with eyeholes **53** located at the top of the screws **50** and **52**, are opposingly inserted into the adjacent vertebrae **54** and **56** below the annulus stent **10**. After insertion of the annulus stent **10** into the aperture **44**, a suture **40** is passed down though the disc annulus **42**, adjacent to

the aperture 44, through the eye hole 53 on the first screw 50 then back up through the disc annulus 42 and through the orifice 18 on the annulus stent 10. This is repeated for the second screw 52, after which the suture 40 is secured. One or more surgical sutures 40 are placed at about equal distances along the sides of the aperture 44 in the disc annulus 42. Reapproximation or closure of the aperture 44 is accomplished by tying the sutures 40 in such a fashion that the sides of the aperture 44 are drawn together. The reapproximation or closure of the aperture 44 enhances the natural healing and subsequent reconstruction by the natural tissue crossing the now surgically narrowed gap in the annulus 42. Preferably, the surgical sutures 40 are biodegradable but permanent
10 ~~non-biodegradable forms may be utilized, nonbio degradable forms may be utilized~~ & This method should decrease the strain on the disc annulus 42 adjacent to the aperture 44, precluding the tearing of the sutures through the disc annulus 42.-

[065] It is anticipated that fibroblasts will engage the fibers of the polymer or fabric 15 of the intervertebral disc stent 10, forming a strong wall duplicating the currently existing condition of healing seen in the normal reparative process.-

[066] In an additional embodiment, as shown in ~~FIGS.~~ FIGS. 10A-B, a flexible bladder 60 is attached to the lower surface 30 of the annulus stent 10. The flexible bladder 20 60 comprises an internal cavity 62 surrounded by a membrane 64, where the membrane 64 is made from a thin flexible biocompatible material. The flexible bladder 60 is attached to the lower surface 30 of the annulus stent 10 in an unexpanded condition. The flexible

bladder 60 is expanded by injecting a biocompatible fluid or expansive foam, as known in the art, into the internal cavity 62. The exact size of the flexible bladder 60 can be varied for different individuals. The typical size of an adult nucleus is about 2 cm in the semi-minor axis, 4 cm in the semi-major axis, and 1.2 cm in thickness.

5

[067] In an alternative embodiment, the membrane 64 is made of a semi-permeable biocompatible material.

10 [068] In an illustrative embodiment, a hydrogel is injected into the internal cavity 62 of the flexible bladder 60. A hydrogel is a substance formed when an organic polymer (natural or synthetic) is cross-linked via, covalent, ionic, or hydrogen bonds to create a three-dimensional open-lattice structure, which entraps water molecules to form a gel. The hydrogelhydroget may be used in either the hydrated or dehydrated form.

15 [069] In a method of use, where the annulus stent 10 has been inserted into the aperture 44, as has been previously described and shown in FIGS.FIGs. 12 A-B, an injection instrument, as known in the art, such as a syringe, is used to inject the biocompatible fluid or expansive foam into the internal cavity 62 of the flexible bladder 60. The biocompatible fluid or expansive foam is injected through the annulus stent 10 into the 20 internal cavity 62 of the flexible bladder 60. Sufficient material is injected into the internal cavity 62 to expand the flexible bladder 60 to fill the void in the intervertebral disc cavity.

The use of the flexible bladder 60 is particularly useful when it is required to remove all or part of the intervertebral disc nucleus.-

[070] The surgical repair of an intervertebral disc may require the removal of the 5 entire disc nucleus, being replaced with an implant, or the removal of a portion of the disc nucleus thereby leaving a void in the intervertebral disc cavity. The flexible bladder 60 allows for the removal of only the damaged section of the disc nucleus, with the expanded flexible bladder 60 filling the resultant void in the intervertebral disc cavity. A major advantage of the annulus stent 10 with the flexible bladder 60 is that the incision area in 10 the annulus 42 can be reduced in size, as there is no need for the insertion of an implant into the intervertebral disc cavity.-

[071] In an alternative method of use, a dehydrated hydrogel is injected into the internal cavity 62 of the flexible bladder 60. Fluid, from the disc nucleus, passes through 15 the semipermeable membrane 64 hydrating the dehydrated hydrogel. As the hydrogel absorbs the fluid the flexible bladder 60 expands, filling the void in the intervertebral disc cavity.

[072] In an alternative embodiment, as shown in FIG. 13, the annulus stent 10 is substantially umbrella shaped, having a central hub 62 with radially extending struts 64. 20 Each of the struts 64 is joined to the adjacent struts 64 by a webbing material 66, forming a radial extension 76 about the central hub 62. The radial extension 76 has an upper surface 68 and a lower surface 70, where the upper surface 68 contours to the shape of

the disc annulus' 42 inner wall. The radial extension 76 may be substantially circular, elliptical, or rectangular in shape. Additionally, as shown in FIG. 20, the upper surface 68 of the radial extension 76 may be barbed 82 for fixation to the disc annulus' 2 inner wall and to resist explosion through the aperture 42.

5 [073] As shown in FIGs. 14 and 15, the struts 64 are formed from flexible material, allowing the radial extension 76 to be collapsed for insertion into aperture 44, then the expand conforming to the shape of the inner wall of disc annulus 42. In the collapsed position, the annulus stent 10 is substantially frustoconical or shuttlecock shaped, and having a leading end 72, comprising the central hub 62, and a tail end 74.

10 [074] In an alternative embodiment, the radial extension 76 has a greater thickness at the central hub 62 edge than at the outside edge.

[075] In an embodiment, the annulus stent 10 is a solid unit, formed from one or more of the flexible resilient biocompatible or bioresorbable materials well known in the art.

15 [076] Additionally, the annulus stent 10 may comprise materials to facilitate regeneration of disc tissue, such as bioactive silica based materials that assist in regeneration of disc tissue as disclosed in U.S. Patent No. 5,849,331 (Ducheyne, et al.), or other tissue growth factors well known in the art.

20 [077] Alternatively, as shown in FIG. 21, a compressible core 84 may be attached to the lower surface 70 of the radial extension 76. The compressible core 84 may be made from one of the biocompatible or bioresorbable resilient foams well known in the art. The compressible core 84 allows the radial extension 76 to be compressed for insertion into

aperture 44 then to expand conforming to the shape of the disc annulus' 42 inner wall and to the cavity created by pathologic extrusion or surgical removal of the disc fragment.

[078] In an additional embodiment, as shown in FIG. 18A and 18B, a flexible bladder 80 is attached to the lower surface 70 of the annulus stent 10. The flexible bladder 80 comprises an internal cavity 86 surrounded by a membrane 88, where the membrane 88 is made from a thin flexible biocompatible material. The flexible bladder 86 is attached to the lower surface 70 of the annulus stent 10 in an unexpanded condition. The flexible bladder 80 is expanded by injecting a biocompatible fluid or expansive foam, as known in the art, into the internal cavity 86. The exact size of the flexible bladder 80 can be varied for different individuals. The typical size of an adult nucleus is 2 cm in the semi-minor axis, 4 cm in the semi-major axis and 1.2 cm in thickness.

[079] In an alternative embodiment, the membrane 88 is made of a semi-permeable biocompatible material.

[080] In a method of use, as shown in FIGs. 16A-16C, the radial extension 76 is collapsed together, for insertion into the aperture 44 of the disc annulus 42. The radial extension 76 is folded such the upper surface 68 forms the inner surface of the cylinder. The annulus stent 10 is then inserted into the aperture 44, inserting the leading end 72 though the aperture 44 until the entire annulus stent 10 is within the disc annulus 42. The radial extension 76 is released, expanding within the disc 44. The upper surface 68 of the annulus stent 10 contours to the inner wall of disc annulus 42. The central hub 62 is

positioned within the aperture 44 so that the annulus stent 10 may be secured to the disc annulus 42 using means well known in the art.

[081] It is anticipated that fibroblasts will engage the fibers of the polymer of fabric of the annulus stent 10, forming a strong wall duplicating the currently existing condition of healing seen in the normal reparative process.

[082] In an alternative method of use, as shown in FIGs. 17A-17C, the radial extension 76 is collapsed together for insertion into the aperture 44 of the disc annulus 42. The radial extension 76 is folded such that the upper surface 68 forms the outer surface of the cylinder. The annulus stent 10 is then inserted into the aperture 44, inserting the tail end 74 through the aperture 44 until the entire annulus stent 10 is in the disc. The radial extension 76 is released, expanding within the disc. The upper surface 68 of the annulus stent 10 contours to the disc annulus' 42 inner wall. The central hub 62 is positioned within the aperture 44 so that the annulus stent 10 may be secured to the disc annulus 42, using means well known in the art.

[083] In an embodiment, the barbs 82 on the upper surface 68 of the radial extension 76 engage the disc annulus' 42 inner wall, holding the annulus stent 10 in position.

[084] In a method of use, as shown in FIGs. 12A-12B, where the annulus stent 10 has been inserted into the aperture 44, as has been previously described. Similarly, for the stent shown in FIGs. 16 through 21, an injection instrument, as known in the art, such as a syringe, can be used to inject the biocompatible fluid or expansive foam into the internal

cavity 86 of the flexible bladder 80. The biocompatible fluid or expansive foam is injected through the annulus stent 10 into the internal cavity 86 of the flexible bladder 80. Sufficient material is injected into the internal cavity 86 to expand the flexible bladder 80 to fill the void in the intervertebral disc cavity. The use of the flexible bladder 80 is particularly useful when it is required to remove all or part of the intervertebral disc nucleus.

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[085] All patents referred to or cited herein are incorporated by reference in their entirety to the extent they are not inconsistent with the explicit teachingsexplicit teachings of this specification, including; U.S. Pat.Patent No. 5,108,438 (Stone), U.S. Pat.Patent No. 10 5,258,043 (Stone), U.S. Pat.Patent No. 4,904,260 (Ray et al.), U.S. Pat.Patent No. 5,964,807 (Gan et al.), U.S. Pat.Patent No. 5,849,331 (Ducheyne et al.), U.S. Pat.Patent No. 5,122,154 (Rhodes), U.S. Pat.Patent No. 5,204,106 (Schepers et al.), U.S. Pat.Patent No. 5,888,220 (Felt et al.) and U.S. Pat.Patent No. 5,376,120 (Sarver et al.).-

15

It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and preview of this application and the scope of the appended claims.Various materials known to those skilled in the art can be employed in practicing the present invention. By means of example only, the body portions of the stent could be made of NiTi alloy, plastics including polypropylene, polyethylene, stainless steel and other biocompatible metals, chromium cobalt alloy, or collagen. Webbing materials can include silicone, collagen, ePTFE,

Dacron, polyester, polypropylene, polyethylene, and other biocompatible materials and can be woven or non-woven. Membranes might be fashioned of silicone, propylene, polyester, SURLYN, PEBAK, polyethylene, polyurethane or other biocompatible materials. Inflation fluids for membranes can include gases, liquids, foams, emulsions, and can be or contain
5 bioactive materials. The stent body, webbing and/or membrane can be drug eluting or bioresorbable, as known in the medical implant arts.

[086] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true
10 scope and spirit of the invention being indicated by the following claims.

Attorney Docket No.: 08442-0002-02-000